

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Office of Field Operations and Response

Office of Emergency Response

Division of Emergency Response

Effective Date: May 13, 2024

1. Division of Emergency Response (DCSHBA).

- A. Provides oversight and leadership to the Food and Drug Administration (FDA) emergency preparedness and response operating the 24-hour, seven-day-a week emergency response system.
- B. Provides oversight and leadership to emergency incidents and situations involving FDA-regulated products and disasters, in conformance with the National Incident Management System (NIMS) and Incident Command System (ICS) principles and practices.
- C. Directs and leads the Office of Inspections and Investigations (OII) emergency preparedness and response activities relative to human and animal food, medical products, and tobacco.
- D. Leads the staffing and other support during Incident Management Group (IMG) activations.
- E. Leads the evaluations of exercises, special events, and OII's response to actual incidents to improve and strengthen OII preparedness for future emergencies.
- F. Leads and coordinates the staffing and other support for National Special Security Events (NSSEs), and other special events, in coordination with the United States Secret Service, Department of Health and Human Services, and the Washington DC Health Department.

2. Field Emergency Response Coordinators Branch 1 (DCSHBA1).

- A. Serves as a federal point of contact for both State and local government, as well as private industry, within the organization during emergencies.
- B. Plans and coordinates outbreak, emergency response, and rapid response team activities.
- C. Provides comprehensive investigational, inspectional, and technical assistance and consultation to OII field managers, and States, concerning the Emergency Response Program.
- D. Evaluates the effects of technological developments on national and regional programs and recommends appropriate policy and procedural changes.
- E. Makes recommendations for improving all levels of local response including, but not limited to, enhancements to training, equipment, organization, and operations.
- F. Coordinates and/or conducts training, exercising, and implementation of the ICS and Incident Management Team (IMT), and any Rapid Response/State emergency response teams.

3. Field Emergency Response Coordinators Branch 2 (DCSHBA2).

- A. Serves as a federal point of contact for both State and local government, as well as private industry, within the organization during emergencies.
- B. Plans and coordinates outbreak, emergency response, and rapid response team activities.
- C. Provides comprehensive investigational, inspectional, and technical assistance and consultation to OII field managers, and States, concerning the Emergency Response Program.
- D. Evaluates the effects of technological developments on national and regional programs and recommends appropriate policy and procedural changes.
- E. Makes recommendations for improving all levels of local response including, but not limited to, enhancements to training, equipment, organization, and operations.
- F. Coordinates and/or conducts training, exercising, and implementation of the ICS and IMT, and any Rapid Response/State emergency response teams.

4. Incident Coordination Branch (DCSHBA3).

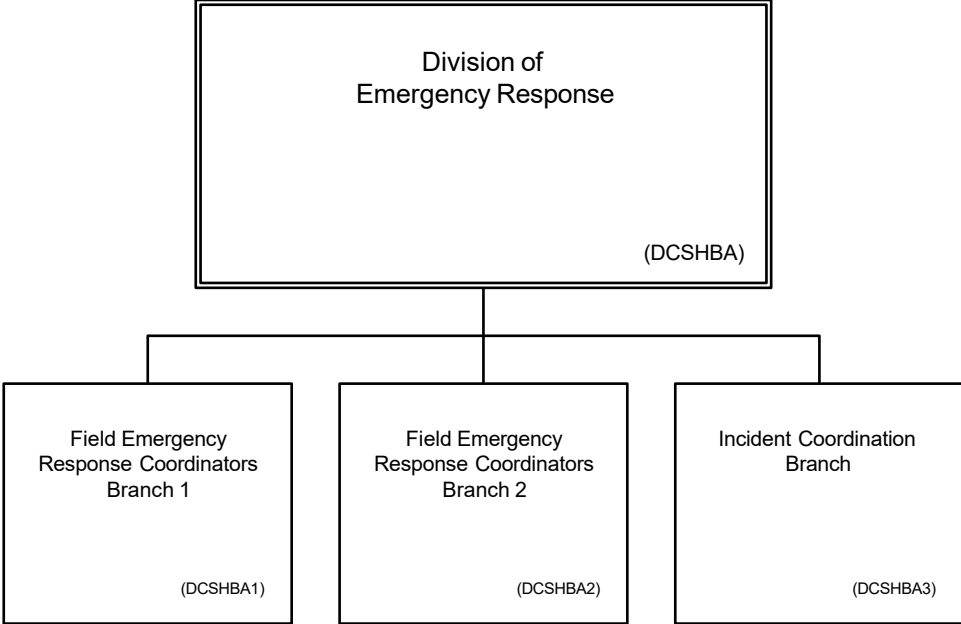
- A. Serves as the FDA emergency preparedness and response operating the 24-hour, seven-day-a week emergency response system.
- B. Coordinates the FDA response to emergency incidents and situations involving FDA-regulated products and disasters, in conformance with NIMS/ICS principles and practices.
- C. Assists in the development and coordination of the FDA's emergency preparedness and response activities by providing analysis of preliminary information about threats and hazards, and assists in the early recognition of emergencies, outbreaks, natural disasters, and terrorism or other criminal acts.
- D. Manages FDA's Emergency Operations Center (EOC) to ensure responses to emergencies or events involving FDA-regulated products follow NIMS/ICS principles.
- E. Coordinates FDA emergency activities with other federal agencies, State, local, tribal, territorial, and foreign government officials, and industry associations.
- F. Represents the FDA at interagency, intra-agency, State, local and foreign government and industry association meetings and conferences on emergency preparedness and response.
- G. Manages the National Consumer Complaint System which monitors reports of potential problems with FDA-regulated products for potential emergencies.
- H. Recommends activation of an IMG to coordinate FDA response to disasters and emergencies involving FDA-regulated products. Responsible for coordinating staffing and operations of IMGs during emergencies.
- I. Monitors international disasters, both natural and man-made, and coordinates with internal FDA and external groups to determine and report the status of staff on official travel in impacted areas.
- J. Monitors and coordinates FDA response to international inquiries directed to FDA from International Food Safety Authority Network (OFOSAN), the European Union's Rapid Alert System for Food and Feed (RASFF), International Health Regulations (IHR) authorities, the HHS IHR contacts, and other international groups.
- K. Provides alert and notification support for the Interagency Advisory Team for the Environmental, Food and Health (A-Team), as required, during activation or potential activation.

- L. Participates in National Biosurveillance Integration Center conference calls, sponsored by the Department of Homeland Security, for interagency information sharing on early recognition of biological events of national concern, both natural and manmade.

5. Authority and Effective Date.

The functional statements for the Division of Emergency Response were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations
Office of Field Operations and Response
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Division of Emergency Response**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Field Operations and Response, Office of Emergency Response, Division of Emergency Response organization structure depicting all the organizational structures reporting to the Director:

Field Emergency Response Coordinators Branch 1 (DCSHBA1)

Field Emergency Response Coordinators Branch 2 (DCSHBA2)

Incident Coordination Branch (DCSHBA3)